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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,596	08/19/2003	Robert C. Getts	4081.011.400	3977

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LAW OFFICE OF MORRIS E. COHEN
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EXAMINER

SISSON, BRADLEY L

ART UNIT PAPER NUMBER

1634

DATE MAILED: 06/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/643,596

Applicant(s)

GETTS, ROBERT C.

Examiner

Bradley L. Sisson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-39 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is drawn to a “method,” however; it is not stated for what the method is drawn. Accordingly, the metes and bounds of the claim cannot be readily determined. Claims 2-5, which depend from claim 1, fail to overcome this issue and are similarly rejected.
3. Claims 6 and 11 are confusing as to how “said first target nucleic acid initially comprises a first capture sequence of nucleic acid.” Whether hybridized to a sequence or not, the claim does not recite any mechanism as to how the first target nucleic acid has been materially changed. Absent a material change, the first target nucleic acid does not comprise a first capture sequence. Rather, a duplex structure comprising a first target nucleic acid and a first capture sequence are hybridized to one another and are subsequently denatured. Claims 7-10, which depend from claim 6, and claims 12-21, which depend from claim 11, fail to overcome this issue and are similarly rejected.
4. Claims 18 and 31 are indefinite wherein is stated, “said assay format is a blot.”
5. Claims 19 and 32 are indefinite wherein is stated, “said assay format is a microarray.”
6. Claims 20 and 33 are indefinite with respect to what constitutes “single channel detection,” as well as just what is being detected and how that relates back to the method of reusing the assay.

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7. Claims 21 and 34 are confusing as to what constitutes “dual channel detection” and what is being detected.

8. Claims 6, 11, and 23 are indefinite with respect to one “reusing an assay.” For purpose of examination, an “assay” has been interpreted as encompassing a series of steps. A review of the claims and disclosure seemingly suggests that applicant is claiming a method of reusing a blot or microarray in an assay, not that an assay per se is being reused. Dependent claims 7-10, 12-22, and 24-39 fail to overcome this issue and are similarly rejected.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 1-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,057,410 (Kawasaki et al.), in view of US 2004/0219569 A1 (Yehiely et al.), US Patent 5,508,188 (Barsky et al.) and US Patent 6,110,687 (Nilsen).

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12. Kawasaki et al., column 14, discloses stripping blots and rehybridizing the immobilized sequences so to detect yet other nucleic acid sequences of interest.

13. Yehiely et al., paragraph 0234, teaches stripping and reuse of a microarray hybridization reaction.

14. Barsky et al., column 8, disclose conditions under which blots were stripped of a hybridized probe such that they could be reused in subsequent hybridization reactions.

15. Nilsen teaches at length the use of dendrimers as a probe for the detection of target sequences.

16. It would have been obvious to one of ordinary skill in the art to combine the methods of Kawasaki et al., Yehiely et al., Barsky et al., and Nilsen as Kawasaki et al., Yehiely et al., and Barsky et al., all teach the stripping of a probe from a blot or microarray such that the blot or microarray could be reused in a subsequent hybridization reaction. Said ordinary artisan would have been motivated to apply the method to where dendrimers are being used in an assay as the binding kinetics is the same as traditional probes, yet affords the ordinary artisan with markedly increased sensitivity.

17. In view of the wide applicability, the detailed teachings, said ordinary artisan would have had a most reasonable expectation of success, and in view of the ability to save financial resources by reusing blots and/or microarrays, said ordinary artisan would have been highly motivated.

18. Therefore, and in the absence of convincing evidence to the contrary, claims 1-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,057,410 (Kawasaki et

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al.), in view of US 2004/0219569 A1 (Yehiely et al.), US Patent 5,508,188 (Barsky et al.) and US Patent 6,110,687 (Nilsen).

Conclusion

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751.

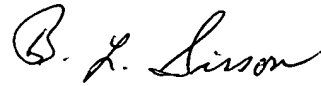
The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

20. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

21. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would

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like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, reading "B. L. Sisson". The signature is written in a cursive, flowing style.

Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
13 June 2006